

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

IN RE: BENICAR (OLMESARTAN)	*	MDL 2606
PRODUCTS LIABILITY LITIGATION	*	
	*	
THIS DOCUMENT RELATES TO	*	JUDGE ROBERT B. KUGLER
ALL CASES	*	
	*	MAG. JUDGE JOEL SCHNEIDER

**PROPOSED JOINT AGENDA AND REPORT  
FOR 30 SEPTEMBER 2015 STATUS CONFERENCE**

**1. Report on Docket.**

There were 1,067 complaints on file with the clerk's office as of September 18, and the U.S. Daiichi defendants had been served with just 511, less than half.

Daiichi Sankyo Company, Limited was served with the Master Complaint on September 7 and filed a Master Answer on September 18.

**PLAINTIFFS' POSITION:**

To the knowledge of the Plaintiffs' Co-Lead Counsel, Plaintiffs are serving Complaints as required under the Federal Rules of Civil Procedure. In light of the filing dates of the Complaints, the number served at this point in time is reasonable. In addition, Defendants just recently provided Plaintiffs with accurate service information for the U.S. Defendants and, just last week, agreed to a streamlined process for service via e-mail.

With regard to Daiichi Sankyo Company, Limited, Plaintiffs will begin serving that entity via certified mail pursuant to the Defendants' agreement with this process. Plaintiffs are hopeful that Defendants will agree to accept service on this entity via e-mail as well. Plaintiffs request entry of an Order providing for service via certified mail, in the event Defendants will not agree to service via email.

**2. State Court Litigation.**

There are currently 65 cases pending in the New Jersey MCL. Judge Nelson C. Johnson, J.S.C. has scheduled a telephonic conference for September 30, 2015 at 12:00 P.M.

**3. Service of Process**

The parties have agreed on an order for streamlined service of process on Daiichi U.S. defendants and the Forest defendants and will present an agreed upon order to the Court.

**4. Duplicate Complaints.**

**DEFENSE POSITION:** Defendants request that the Court address the status of “double dipper” cases; lawsuits filed twice by the same plaintiff through different attorneys making the exact same complaints. The cases at issue are: Roberson v. Daiichi Sankyo, Inc., et al., No. 1:15-cv-04341, filed June 24, 2015, by Levin, Papantonio, Thomas, Mitchell, Rafferty & Proctor, PA and Roberson v. Daiichi Sankyo, Inc., et al., No. 1:15-cv-04475, filed June 25, 2015, filed by GoldenbergLaw, PLLC. Counsel for defendants wrote to both of plaintiff’s lawyers on July 16, 2015, requesting that they specify which lawyer represents plaintiff and to dismiss with prejudice the second lawsuit. Despite multiple follow-ups by Defendants throughout the months of July and August, neither lawyer responded to Defendants’ letter and request for dismissal. Nearly three months have passed since the filing of these lawsuits. The lawyers’ failure to respond has left Defendants with no choice but to seek Court intervention.

**PLAINTIFFS’ POSITION:**

Plaintiffs’ Co-Lead Counsel has addressed this issue with the appropriate Plaintiffs’ firms. Plaintiffs anticipate the issue being resolved by the September 30, 2015, status conference.

**5. Plaintiff Fact Sheets.**

Of the 39 PFSs received as of September 25, 2015, 18 are not substantially complete and 17 do not identify sprue like enteropathy or one of the listed serious gastrointestinal injuries.

**PLAINTIFFS' POSITION:**

Defendants first brought this issue to Plaintiffs' Co-Lead Counsel's attention on Friday, September 25, 2015. Consequently, the parties have not had an opportunity to meet and confer about this. Because the term "substantially complete" is subject to interpretation, and since Plaintiffs' Co-Lead Counsel has not yet seen the PFSs at issue, Plaintiffs suggest that the parties meet and confer to work towards a resolution of the issue.

**6. Discovery from the Defendants.**

The three groups of defendants collectively (Daiichi Japan, Daiichi U.S. and Forest) have produced over 5 million pages of documents, including regulatory submissions such as the Investigational New Drug Applications and New Drug Applications for Benicar®, Benicar HCT®, Azor®, and Tribenzor®, departmental file documents, custodial electronic mail and paper documents, adverse event reports, FDA correspondence, marketing documents, detail representative training materials, and other data and documents. Defendants have spent more than \$7.2 million on document collections and productions to date.

Defendants have each responded to 197 requests for production of documents, including sub parts, in the New Jersey State Court Litigation, which apply as served in the MD, 156 requests for admissions in the New Jersey State Court Litigation, which apply as served in the MDL, and served over 53 letters supplementing discovery responses as well as 78 interrogatories, including subparts, 74 requests for production of documents, including subparts in the MDL, 30 ROADMAP requests for production of documents in the MDL.

**PLAINTIFFS' POSITION:**

Defendants have been repeatedly telling the Court that over 5 million pages of documents have been produced. Plaintiffs look forward to the production of the millions of pages of relevant documents that have not yet been produced, as well as production of the custodial files from all Defendants, pursuant to the agreed search terms, including Daiichi Japan as soon as those search terms are set.

**7. Bellwether Cases.**

**DEFENSE POSITION:** Defendants agree with Judge Kugler's suggestion that Bellwether cases should be chosen randomly. This Court's sentiments are supported by the empirical evidence cited in a recent article in the Akron Review of Law. Loren H. Brown, Matthew A. Holian, Arindam Ghosh, *Bellwether Trial Selection in Multi-District Litigation: Empirical Evidence in Favor of Random Selection*, 47 Akron Rev. of L. 663 (2014). ("With random selection, the court and parties should feel more confidence in the process and be able to place more weight in the results of bellwether trials, which helps ensure that the bellwether process accomplishes its objections.") *Id.* at 690-91.

The Manual for Complex Litigation states that the benefit of bellwether trials is that "the specific plaintiffs and their claims should be representative of the range of cases," and to meet this goal, "a judge should direct the parties to select test cases randomly or limit the selection to cases that the parties agree are typical of the mix of cases." Manual for Complex Litigation (Fourth) § 22.315 (2004). Similarly, the Fifth Circuit, in an opinion criticizing the district court's decision to allow each side to pick fifteen bellwether cases, stated:

A bellwether trial designed to achieve its value ascertainment function for settlement purposes or to answer troubling causation or liability issues common to the universe of claimants has a core element representativeness – that is, the

sample must be a randomly selected one of sufficient size so as to achieve statistical significance to a desired level of confidence in the result obtained.

In re Chevron U.S.A., Inc., 109 F.3d 1016, 1019 (5th Cir. 1997) (emphasis added). Other MDL courts have implemented random selection into at least part, if not all, of the bellwether selection process. See, e.g., In Re Xarelto Prods. Liab. Litig., No. 2:14-md-025920EEF-MBN (E.D. La. September 18, 2015) (Twenty of forty cases to be randomly chosen); In re Mirena IUD Prods. Liab. Litig., No. 7:13-md-2434-CS-LMS, Dkt. 2401 at (S.D.N.Y. May 14, 2015) (“An additional five cases shall be chosen at random from all cases which have been filed an a Plaintiff Fact Sheet with Core Criteria completed and served as of May 1, 2015.”); In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig., No. 3:05-md-1699-CRB, Dkt. 751 at 2 (N.D. Cal. Nov. 17, 2006) (“Ten of the Plaintiffs shall be selected by the [PSC]; ten of the Plaintiffs shall be selected by [Pfizer]; and twenty-five of the Plaintiffs shall be selected randomly.”); In re Prempro Prods. Liab. Litig., No. 4:03-cv-1507-BRW, Dkt. 671 at 2 (E.D. Ark. June 20, 2005) (“From this list of cases, I will randomly draw from a hat (literally) fifteen cases.”); In re Norplant Contraceptive Prods. Litig., MDL No. 1038, 1996 WL 571535, at \*1 (E.D. Tex. Aug. 12, 1996) (“From this pool, the parties will randomly select a group of twenty-five plaintiffs.”).

As discussed with Judge Schneider on September 24, 2015, the Defendants would like additional time to submit a written response to Plaintiffs’ proposal and meet and confer with Plaintiffs.

#### **PLAINTIFFS’ POSITION:**

Plaintiffs served Defendants with a written proposal for bellwether selection on August 31, 2015. Despite Plaintiffs’ multiple follow-up communications on this issue, Defendants have not responded, and have apparently chosen not to meet and confer.

Plaintiffs' proposal provides for each side to select nine (9) representative bellwether cases as part of the Initial Bellwether Discovery Pool. Following initial limited discovery concerning all eighteen (18) cases, the parties shall each simultaneously select six (6) cases from the Initial Bellwether Discovery Pool to proceed to the Bellwether Trial Pool. Along with the lists, the parties are to provide the Court with letter briefs, not to exceed two (2) pages per case, with a description of each case and why it is a representative case that should be included as a Trial Pool case. Under Plaintiffs' proposal, the Court will then select six (6) cases, three (3) from the Plaintiffs' proposed Bellwether Trial Pool selections and three (3) from the Defendants' proposed Bellwether Trial Pool selections, to proceed to the Final Bellwether Trial Pool.

Plaintiffs believe this proposal to be the best method for reaching a representative pool of cases. Plaintiffs have considered bellwether selection orders from other district judges handling MDL cases, and a process similar to this has been adopted by many courts. *See In re: Yasmin and Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, Dkt.1329 (S.D. Ill. October 13, 2010); *In re: Actos (Pioglitazone) Prods. Liab. Litig.*, No. 6-11-md-2299, Dkt. 2359 (W.D. La. February 19, 2013); and *In re: Pradaxa (Dabigatran Etexilate) Prods. Liab. Litig.*, No. 3:12-md-02385-DRH-SCW, Dkt. 154 (S.D. Ill. April 9, 2013).

Although the District Court *In re: Yasmin and Yaz* considered the Complex Litigation Manual's reference to random selection, the court simply felt that it was best not to take a chance with random selection, finding that "[m]ost modern plans seem to disfavor random selection in order to have better control over the representative characteristics of cases selected." *In re: Yasmin and Yaz*, Dkt. 1329 at 5 (citing Eldon E. Fallon, Jeremy T. Grabill & Robert Pitard Wynne, *Bellwether Trials in Multidistrict Litigation*, 82 TUL. L. REV. 2323, 2349-51 (2008)) (discussing various methods for populating the pool of potential bellwether cases); *See, e.g., id.*

at n. 95 (discussing the bellwether selection process in the Guidant Defibrillators Products Liability Litigation (allowing each party to select an equal number of cases to populate the pool) and noting the court's preference for party input in selecting representative cases).

Ultimately, in rejecting a process involving random selection, Judge Herndon in *In re Yasmin and Yaz* concluded:

The most critical element of this plan [Bellwether Trial Selection Plan] and the purpose it seeks to serve is for the most representative cases to be selected and for no one to lose sight of that objective. . . Together, however, they [the parties] share a common interest in this phase of the litigation, which is to put together a list of cases that most accurately represent the typical case at issue in this litigation. . . Little credibility will be attached to this process, and it will be a waste of everyone's time and resources, if cases are selected which do not accurately reflect the run-of-the mill case.

*In re Yasmin and Yaz*, *supra*, at 4-5, ¶ 3. Plaintiffs share this same conviction and strongly believe that the bellwether process becomes meaningless if representative cases are not worked up as bellwether selections, instead of random selections that might include outlier cases that will not advance the resolution of this litigation.

Dated: September 28, 2015

Respectfully Submitted,

/s/ Susan M. Sharko  
Susan M. Sharko  
[susan.sharko@dbr.com](mailto:susan.sharko@dbr.com)  
Lead Counsel for the Defendants  
**DRINKER BIDDLE & REATH LLP**  
600 Campus Drive  
Florham Park, NJ 07932  
PH: (973) 549-7000  
FAX: (973) 360-9831

/s/ Michael C. Zogby  
Michael C. Zogby  
[michael.zogby@dbr.com](mailto:michael.zogby@dbr.com)  
Defendants' Liaison Counsel  
**DRINKER BIDDLE & REATH LLP**

600 Campus Drive  
Florham Park, NJ 07932  
PH: (973) 549-7000  
FAX: (973) 360-9831

/s/ Christopher L. Coffin  
Christopher L. Coffin  
[ccoffin@pbclawfirm.com](mailto:ccoffin@pbclawfirm.com)  
Co-Lead Counsel for the Plaintiffs  
***Pendley, Baudin & Coffin, L.L.P.***  
1515 Poydras Street, Suite 1400  
New Orleans, LA 70112  
PH: (504) 355-0086  
FAX: (504) 523-0699

/s/ Adam M. Slater  
Adam M. Slater  
[alsater@mskf.net](mailto:alsater@mskf.net)  
Co-Lead Counsel for the Plaintiffs  
***Mazie Slater Katz & Freeman LLC***  
103 Eisenhower Parkway  
Roseland, New Jersey 07068  
PH: (973) 228-9898  
FAX: (973) 228-0303

/s/ Richard M. Golomb  
Richard M. Golomb  
[rgolomb@golombhonik.com](mailto:rgolomb@golombhonik.com)  
Liaison Counsel for Plaintiffs  
***GOLOMB & HONIK***  
1515 Market Street, Suite 1100  
Philadelphia, PA 19102  
PH: (215) 985-9177  
FAX: (215) 985-4169